

Norman C. Kleinberg (NK 2735)  
Theodore V. H. Mayer (TM 9748)  
William J. Beausoleil (WB 5296)  
HUGHES HUBBARD & REED LLP  
One Battery Park Plaza  
New York, New York 10004-1482  
(212) 837-6000

*Attorneys for Defendant Merck & Co., Inc.*

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:
Fosamax Products Liability Litigation	: 1:06-md-1789 (JFK)
	:
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<i>This Document Relates to:</i>	:
Mary Casteel	:
v. Merck & Co., Inc.	:
	:
Case No: 1: 07-cv-2821-JFK	:
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**ANSWER AND AFFIRMATIVE  
DEFENSES OF MERCK  
& CO., INC.;  
DEMAND FOR JURY TRIAL**

Defendant, Merck Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

**PARTIES**

1. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 1.
2. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in Whitehouse Station, New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 2.
3. Merck admits that it is registered to do business in the State of New York.

**JURISDICTION**

4. The allegations of Paragraph 4 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 4, except for jurisdictional purposes only admits that Plaintiff seeks in excess of \$75,000.

**FACTUAL BACKGROUND**

5. Merck denies each and every allegation of Paragraph 5, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information.

6. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 6 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text.

7. Merck denies each and every allegation of Paragraph 7, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 7 inconsistent with that prescribing information and respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text.

8. Merck denies each and every allegation of Paragraph 8.

9. Merck denies each and every allegation of Paragraph 9.

10. Merck denies each and every allegation of Paragraph 10, except that Merck states that on January 31, 2005, it received a request dated January 24, 2005 from the FDA to update the label for FOSAMAX® to include bisphosphonate class labeling for ONJ. Merck submitted a draft revised label to the FDA on March 1, 2005. FDA comments on this draft revised label were received in June 2005, and the new label was made publicly available in July 2005.

11. Merck denies each and every allegation of Paragraph 11.

12. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 12.

13. Merck denies each and every allegation of Paragraph 13.

14. Merck denies each and every allegation of Paragraph 14, including each and every allegation of subparts (a) through (g).

**FIRST CLAIM FOR RELIEF**

[STRICT PRODUCT LIABILITY – DESIGN DEFECT]

15. Merck repleads its answers to Paragraphs 1 through and including 14, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

16. Merck denies each and every allegation of Paragraph 16, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 22.

**SECOND CLAIM FOR RELIEF**

[STRICT PRODUCT LIABILITY – FAILURE TO WARN]

22. Merck repleads its answers to Paragraphs 1 through and including 21, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

23. Merck denies each and every allegation of Paragraph 23, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

**THIRD CLAIM FOR RELIEF**

[NEGLIGENCE]

27. Merck repleads its answers to Paragraphs 1 through and including 26, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

28. Merck denies each and every allegation of Paragraph 28, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

29. The allegations in Paragraph 29 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, Merck

respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

**FOURTH CLAIM FOR RELIEF**

[BREACH OF EXPRESS WARRANTY]

33. Merck repleads its answers to Paragraphs 1 through and including 32, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

34. Merck denies each and every allegation of Paragraph 34, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

35. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

**FIFTH CLAIM FOR RELIEF**

**[BREACH OF IMPLIED WARRANTY]**

38. Merck repleads its answers to Paragraphs 1 through and including 37, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

39. Merck denies each and every allegation of Paragraph 39, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

40. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

**PRAYER FOR RELIEF**

WHEREFORE, Merck denies that Plaintiff is entitled to any of the relief requested in the Prayer for Relief, and Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon

completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

**FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

**SECOND AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

**THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**SEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

**EIGHTH AFFIRMATIVE DEFENSE**

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

**NINTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**TENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.



**ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

**TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, New York, and Tennessee Constitutions.

**THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available

medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff has not suffered any actual injury or damages.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claimed are barred under the doctrine of economic loss.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims which are based on allegations of fraud have not been plead with sufficient particularity.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

To the extent Plaintiff makes a claim for punitive damages, Merck asserts that such Plaintiff has not complied with statutory requirements to recover punitive damages.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

The asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

The substantive law of Tennessee applies to Plaintiff's claims.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

To the extent the Plaintiff's claims are based upon any theory of product liability, they are barred or limited by Tennessee's Product Liability Act, Tenn. Code Ann. §29-28-101 *et seq.*, and Merck affirmatively asserts all defenses available therein.

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

The Complaint fails to state an amount for which Plaintiff sues as required by the Tennessee Product Liability Act of 1978, T.C.A. § 29-11-101 *et seq.*, thereby barring plaintiff's recovery.

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Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees as may be available by law, together with such and other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Defendant hereby demands a trial by jury.

DATED: New York, New York  
June 11, 2006

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: \_\_\_\_\_  
Norman C. Kleinberg (NK 2735)  
Theodore V. H. Mayer (TM 9748)  
William J. Beausoleil (WB 5296)

One Battery Park Plaza  
New York, New York 10004-1482  
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*Attorneys for Defendant Merck & Co., Inc.*